Consensus conference on laparoscopic liver resection: a jury-based evaluation

Clavien, Pierre-A ; Barkun, Jeffrey

DOI: https://doi.org/10.1097/SLA.0000000000001183

Consensus Conference on Laparoscopic Liver Resection

A Jury-based Evaluation

*Pierre-A. Clavien, MD, PhD, FACS (Hon) *† and Jeffrey Barkun, MD, MSc, FRCSC‡*

The introduction and rapid development of laparoscopy over the past 2 decades has triggered a revolution in most surgical fields, starting with the removal of the gallbladder, but rapidly moving toward more sophisticated types of procedures. The impetus for this success was the ability to perform surgery without large scar, with the hope of less suffering and faster recovery. No surprise that this new approach was rapidly accepted or even demanded by many patients. Laparoscopic approaches, however, were usually introduced by a number of "innovators"[1] without proper assessment or rigorously conducted studies. Claims of safety or even superiority were most often based on small case series or even a single case. The past decade has seen the same enthusiasm with the availability of robotic surgery.

How to objectively assess laparoscopic approaches in a timely way compared to standard procedures remains an extraordinary task. The generation of high-quality comparative data is often preempted by patient-derived pressure for the technology,[2] by "innovator"-surgeons and industry to develop and promote less traumatic approaches, or by the relentless competition among centers and health professionals to attract patients. Patients and referring physicians may therefore be faced with usually incomplete and often biased information resulting in the choice of novel approaches with questionable improved efficacy and unclear safety. To address these issues, a group of epidemiologists, trialists, and surgeons met several times over a 3-year period at the Balliol College in Oxford, England, to develop a new and pragmatic approach on how to evaluate novel technologies and devices; this exercise is known as the "Balliol collaboration."[3–5] It led to the "IDEAL" paradigm (I: innovation, D: development, E: evaluation, A: assessment, and L: long-term evaluation) offering an appealing way to evaluate new innovations, as they are being introduced into practice, step by step and in a timely fashion.

Laparoscopic and robotic approaches targeting many types of procedures are fitting examples on how "IDEAL" may apply. A procedure may very rapidly climb the IDEAL scale through fast-track adoption and promotion, as did laparoscopic cholecystectomy, but the procedure may ultimately not be efficacious, cost-effective, or safe in the short or long-term as for renal artery denervation for ambulatory hypertension, the transvaginal placement of pelvic floor mesh[6] for stress urinary incontinence, or the use of metal on metal hip prostheses.

Laparoscopic liver resection (LLR) has followed a different and slower path with reports in the literature dating as far back as 1992.[7] The first structured case-series appeared only in 2000,[8] and the procedure has been championed by a small number of either experienced hepatobiliary surgeons, who learned complex laparoscopic approaches, or skilled minimally invasive general surgeons, who applied their innovative expertise to a complex field in which they were originally novices. Currently, most reports still rely on small case series, case reports, or videos. This was also the general context of the first consensus conference among experts, which took place in Louisville, Kentucky, in 2008.[9] The format of that conference was a meeting of innovators primarily sharing expertise and opinions to generate a set of important statements, sensibly promoting the novel approach. The subsequent 5 years has seen a dramatic increase in the number of liver resections performed laparoscopically including major hepatectomies for a variety of indications, even in healthy living liver transplantation donors. A number of systematic reviews or meta-analyses based on observational data have also been reported.

As a strong promoter of LLR, Professor Go Wakabayashi (Morioka, Iwate, Japan) organized in October 2014, the second international conference of experts in LLR involving most of the original Louisville conference participants. The novelty of this conference consisted in the addition of an independent Jury according to the Zurich-Danish model of consensus conference,[10] and the use of

From the *Department of Surgery, University Hospital Zurich, Zurich, Switzerland; †Hôpital Paul Brousse, Université Paris Sud, Paris, France; and ‡Department of Surgery, McGill University, Montreal, Canada.

Disclosure: The authors declare no conflicts of interest.

Reprints: Pierre-A. Clavien, Department of Surgery, University Hospital Zurich, Raemistrasse 100, CH-8091 Zurich, Switzerland. E-mail: clavien@access.uzh.ch.

ISSN: 0003-4932/15/26104-0630
DOI: 10.1097/SLA.0000000000001183

GRADE[11] to evaluate existing evidence. The main characteristic of this model is that the final recommendations are the sole responsibility of the independent Jury members. Such formats have been previously successfully developed to assess the role of liver transplantation to treat patients with liver cancer[12] or the treatment of liver metastases from neuroendocrine tumors[13] or how to select chairs for departments of academic medicine.[14] For the purpose of evaluating LLR, it was felt that the jury must have profound knowledge of liver surgery, although not include obvious promoters or opponents of the laparoscopic approach. The jury was, therefore, composed of experienced liver surgeons from different parts of the world including a few with particular knowledge in epidemiology and consensus conferences. Of note, 3 members of the Jury had been involved with the Balliol collaboration (including the jury president, and both authors of this editorial). The international jury was exclusively made up of surgeons covering the 5 continents with long-standing expertise in open liver surgery, yet without publications in favor or against laparoscopic liver surgery. At the time of the Japan conference, a number of engaged experts in LLR became anxious about putting their "beliefs" and expertise in the hand of nonlaparoscopic liver surgeons in this conference model, apprehending conservative and perhaps negative judgments.

The original report of the consensus conference is published in this issue of *Annals of Surgery*, as a featured article.[15] The article reports on 2 sets of recommendations: those of the Jury based on data presented by the experts at the conference, and the recommendation of the experts especially targeting technical aspects of LLR, such as the use of hand-assisted, hybrid, or pure laparoscopic approaches. The statements are presented with the respective levels of evidence according to GRADE (weak, moderate, or strong recommendation)[11] and the degree of recommendation is adapted to the Zurich-Danish model.[10]

The dual set of recommendations should be seen as complementary. They are the result of a highly productive and robust evaluation of many data of primarily low evidence. The data continue to reflect both enthusiasm and positive results at the hands of experts. As well as compiling these data, the LLR experts also prepared invaluable statements relating to technical aspects of LLR, although the distinction between the jury-driven recommendations and those made by the experts must be clearly discriminated. The jury recommendations are based on data that, albeit comparative, are still prone to the possibility of selection bias related to the indications for, and the very feasibility of, LLR. In fact, the exact proportion of major LLR versus open resection being performed in the practices of the contributing experts remains either estimated or undefined. For this reason, the surgical community eagerly anticipates greater information of higher level of evidence from two randomized trials, which are currently recruiting. These are designed to be powered to answer questions regarding the possible benefits of LLR regarding postoperative complications and early recovery after major resection. It is also necessary to state that the favorable recommendations put forward by the *Annals of Surgery* article require caution on a backdrop of isolated reports of clustered mortality, which highlights the need for a safe introduction of major LLR.[16] This may best be monitored in the context of a broader-based registry, and through the identification of cases that should be deferred depending on one's individual learning curve of LLR.

In summary, this impressive and thoughtful exercise was well-prepared and discussed over an intense 3-day period, laying the basis for our most up-to-date understanding and assessment of LLR and its future directions.

REFERENCES

1. Rogers EM. Lessons for guidelines from the diffusion of innovations. *Jt Comm J Qual Improv*. 1995;21:324–328.
2. Wilson CB. Adoption of new surgical technology. *BMJ.* 2006;332:112–114.
3. Barkun JS, Aronson JK, Feldman LS, et al. Evaluation and stages of surgical innovations. *Lancet.* 2009;374:1089–1096.
4. Ergina PL, Cook JA, Clavien PA, et al. Challenges in evaluating surgical innovation. *Lancet.* 2009;374:1097–1104.
5. McCulloch P, Altman DG, Campbell WB, et al. No surgical innovation without evaluation: the IDEAL recommendations. *Lancet.* 2009;374:1105–1112.
6. US Food and Drug Administration. UPDATE on serious complications associated with transvaginal placement of surgical mesh for pelvic organ prolapse: FDA safety communication. Available at: http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm262435.htm. Accessed February 9, 2015.
7. Gagner M, Rheault M, Dubuc J. Laparoscopic partial hepatectomy for liver tumor (abstract). *Surg Endosc*. 1992;6:99.
8. Cherqui D, Husson E, Hammoud R, et al. Laparoscopic liver resections: a feasibility study in 30 patients. *Ann Surg*. 2000;232:753–762.
9. Buell JF, Cherqui D, Geller DA, et al. The international position on laparoscopic liver surgery: the Louisville statement, 2008. *Ann Surg.* 2009;250:825–830.
10. Lesurtel M, Perrier A, Bossuyt PM, et al. An independent jury-based consensus conference model for the development of recommendations in medico-surgical practice. *Surgery.* 2014;155:390–397.
11. Guyatt GH, Oxman AD, Vist GE, et al. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. *BMJ*. 2008;336:924–926.
12. Clavien PA, Lesurtel M, Bossuyt PM, et al. Recommendations for liver transplantation for hepatocellular carcinoma: an international consensus conference report. *Lancet Oncol.* 2012;13:e11–e22.
13. Frilling A, Modlin IM, Kidd M, et al. Recommendations for management of patients with neuroendocrine liver metastases. *Lancet Oncol.* 2014;15:e8–e21.
14. Clavien PA, Deiss J. Selecting chairs for departments of academic medicine. *Nature* 2015. In press.
15. Wakabayashi G, Cherqui D, Geller DA, et al. Recommendations for laparoscopic liver resection: a report from the second International Consensus Conference held in Iwate. *Ann Surg*. 2015;261:619–629.
16. KYODO. Gunma hospital reveals ninth death following laparoscopic surgery. *The Japan Times*. November 19, 2014.